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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,268	12/18/2006	Tove Ringerike	76222-PCT-US/GJG	2090
23432 7590 06/09/2010 COOPER & DUNHAM, LLP 30 Rockefeller Plaza 20th Floor NEW YORK, NY 10112				
			EXAMINER HIBBERT, CATHERINE S	
			ART UNIT 1636	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,268

Applicant(s)

RINGERIKE ET AL.

Examiner

CATHERINE HIBBERT

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8,9,11-13,15,16,24 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 52 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4,8,44 and 45 is/are allowable.
- 6) ☒ Claim(s) 9,11-13, 15-16 and 46-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' Amendments to the Claims filed 12 March 2010 is received and entered. Applicants' Amendment to the Drawings filed 12 March 2010 is received and entered. This US Application 10/577,268 filed 26 April 2006, is a 371 National Stage entry of PCT/PL2004/000075, filed 26 September 2004, which claims foreign priority to PCT/PL2003/00098, filed 26 September 2003. Claims 1-3, 5-7, 10, 14, 17-23 and 25-43 are cancelled. Claims 44-52 are new. Claims 4, 8-9, 11-13, 15-16, 24 and 44-52 are pending. Claims 24 and 52 are withdrawn to non-elected subject matter. Claims 4, 8-9, 11-13, 15-16 and 44-51 are under examination in this action. As some of the new grounds of rejection presented herein were not necessitated by amendment, this action is **non-final**.

Election/Restrictions

Upon further consideration and search, the species election requirement for claims 4, 8, 44 and 45 is withdrawn and the species therein pertaining to SEQ ID NO's 1-35 are rejoined.

Newly submitted claim 52 is directed to the non-elected invention group II (Group II contains claim 24). Accordingly, claim 52 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants' request for rejoinder of claim 24 (page 9 of Remarks submitted 3/12/210) is acknowledged; Applicants state that claim 24 "is a method of use of an elected product and contains all limitations of claim 9". However, because claim 9 has not been found allowable, the examiner notes that claims 24 and new claim 52 are

withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 July 2009.

Examiner's note: In addition, it is noted for clarity of the record that the newly added claims 44-52 are being examined to the extent they read on the following elected species: "EL4 T-cells" (e.g. as type of cell line), and "the cell line EL/p1-5' IL2-dEGFP/6" (e.g. as type of cell line). Election of species was made **without** traverse in the reply filed on 29 July 2009.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Poland on 26 September 2003. It is noted, however, that applicant has not filed a certified copy of the PCT/PL2003/00098 application as required by 35 U.S.C. 119(b).

Drawings

The objection to the Drawings is **withdrawn** due to Applicants' Amendment to the Drawings filed 12 March 2010.

Response to Amendments/Arguments

The rejection of claims 4, 8-9, 11-13 and 15-16 under 35 U.S.C. 112, second paragraph, is **withdrawn** based on claim amendments. The rejection of cancelled claims 1-3 and 5-7 is moot.

The rejections of Claims 9, 11-13 and 15 under 35 U.S.C. 102(b) as being anticipated by Frazer et al and as being anticipated by Glimcher et al are **withdrawn** based on claim amendments. The rejections of cancelled claims 1-3 and 5-7 are moot.

Any rejection/objection not repeated herein is withdrawn.

New grounds of objection/rejection

Specification

The disclosure is objected to because of the reasons provided below under 35 U.S.C. § 112, first paragraph, and for the following informalities: Page 16, line 15 contains the typographical error “trough”, page 25, line 16, contains a typographical/grammatical error in the term “details” and page 41, line 25 contains a typographical error in the term “previos”. Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to and claims 9, 11-13, 15-16 and 46-51 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, because the specification does not provide evidence that the claimed

biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited.

Because it is not clear that cell lines possessing the exact properties of the cell line listed in claim 16 and Table 3 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of cell lines listed in claim 16 and Table 3, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell lines is an unpredictable event. Note that the best mode is not satisfied by a written disclosure unless the exact embodiment is reasonably reproducible from that disclosure. If reproducibility of the cell line is not established, failure to deposit the cell line would result in concealment of the best mode contemplated by applicant for carrying out the invention. *In re Sherwood*, 615F.2d 809,204 USPQ 537 (CCPA 1980). Although Applicant has disclosed the deposit of the cell lines shown in Table 3 and provided provisional accession numbers assigned by the ECACC (European Collection of Animal Cell Cultures), this is an insufficient assurance that the deposit has been made and all the conditions of MPEP 608.01 (p)(c) met.

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an

International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Applicant's provision of these assurances would obviate this objection/rejection.

Affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of the deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a

position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9, 11-13, 15-16 and 46-51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The term "single-celled host" is not defined by the specification, however, the term is partially defined by the instant claim 11, for example, as encompassing mammalian cells as well as eukaryotic cell lines. As mammals are not single-celled organisms and since the claim distinguishes mammalian cells from eukaryotic cell lines, the recitation of a single-celled host reads on a cell that is present or intended to be present in a human being, which is non-statutory subject matter. As such, the recitation of the limitation "non-human" mammalian cells would be remedial. See 1077 O.G. 24, April 21, 1987.

Conclusion

Claims 4, 8, 44 and 45 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

Respectfully submitted,

Catherine Hibbert
Examiner AU1636